Supreme Court, U.S.
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No. 10-412

In The Supreme Court of The United States

VANDERBILT UNIVERSITY,
Petitioner,

v.

ICOS CORPORATION,
Respondent.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

PETITIONER'S REPLY BRIEF

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RULE 29.6 STATEMENT

The Corporate Disclosure Statement included in the Petition for a Writ of Certiorari remains accurate.

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REPLY BRIEF FOR PETITIONER

ICOS acknowledges that the Federal Circuit's imposition of a clear-and-convincing-evidence standard on Section 256 actions arises from that court's imposition of that standard on Section 282 invalidity claims. Opp. 24, n.8. This Court has recognized that the imposition of that heightened standard, where there is no evidence that Congress intended such a standard, is an important issue worthy of this Court's review. *See Microsoft Corp. v. i4i Limited Partnership* (No. 10-290). Confronted with this fact, ICOS devotes the majority of its opposition to an evidentiary argument that the imposition of a preponderance-of-evidence standard could not possibly affect the outcome of Vanderbilt's claim; an argument made possible only by ICOS' mischaracterization of the District Court's findings and failure to acknowledge the contrary view of the Court of Appeals. ICOS' fallback position---that Congress codified a pre-existing clear-and-convincing-evidence standard for actions to correct the inventors on a patent in the Patent Act of 1952---is wrong and disingenuous. No such cause of action existed prior to the Act.

The Court should grant Vanderbilt's petition for the same reasons raised in *Microsoft* as Vanderbilt's case is actually a better vehicle for the Court to consider the burden of proof issue. If the Court does not grant Vanderbilt's petition outright the Court should hold Vanderbilt's petition pending a decision in *Microsoft* because that decision is likely to impact the outcome of Vanderbilt's case. Acknowledging that possibility, ICOS suggests that the Court could reasonably establish a rule in *Microsoft* that the preponderance-

of-evidence standard applies to all claims of invalidity, or even just those based upon information not considered by the PTO, but retain a higher clear-and-convincing-evidence standard in Section 256 cases. Opp. 2, 3, 13, 24-25. If that was the case an accused infringer would have a lesser burden *to invalidate a patent* by proving that a patent failed to list a joint inventor than the misjoined or unnamed inventor would have in a claim *to preserve the patent's validity* through correction under Section 256. The absurdity of such a result is obvious. If the standard changes for Section 282 it must change for Section 256.

I. THE STANDARD OF PROOF ISSUE RAISED IN VANDERBILT'S PETITION IS WORTHY OF REVIEW BY THIS COURT

A. Vanderbilt Has Raised an Important Issue of Law

As this Court has noted, "[b]ecause the Federal Circuit has exclusive jurisdiction over appeals from all United States District Courts in patent litigation," when that Court repeatedly misconstrues some aspect of the law in that area "it is a matter of special importance to the entire Nation" that warrants this Court's review notwithstanding a lack of conflicting decisions from other circuits. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993).[1] This is true

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[1] The imposition of the clear-and-convincing evidence standard on Section 256 claims is arguably in conflict with pre-1982 opinions from other circuits that preponderance of the evidence was the appropriate burden in the invalidity context. *See Manufacturing Research Corp. v. Graybar Electric Co.*, 679 F.2d 1355, 1360-61

where the Federal Circuit imposes a rule on a section of the Patent Act inconsistent with Congress' intent as reflected in the text. *Pfaff v. Wells Electronics, Inc.* 525 U.S. 55, 60 (1998). Section 256 makes no reference to the heightened clear-and-convincing-evidence burden of proof imposed by the Court of Appeals. Thus, even if Vanderbilt's petition was limited to the issue of whether the Court of Appeals erred in imposing that burden, the petition should be granted.

ICOS concedes that neither the text nor legislative history of Section 256 reflect a Congressional intent to impose a heightened burden on parties seeking to correct a patent. However, ICOS asserts that prior to the passage of the Patent Act of 1952 courts had established a clear-and-convincing-evidence standard in such cases and that Congress intended to codify that standard into Section 256. Opp. 21. Quite the contrary, Section 256 created an entirely new cause of action.

The Patent Act of 1952 only "partly" codified the common law of patents that had evolved prior to that time. Karl B. Lutz, *The New 1952 Patent Statute*, 35 J. Pat. & Trademark Off. Soc'y 156, 157 (1953). Entitled "An Act *to revise* and codify the laws relating to patents and the Patent Office, and to enact into law Title 35 of the United States Code entitled, 'Patents,'" (emphasis added), it also made "liberalizing changes."

(11th Cir. 1982); *Baumstimler v. Rankin*, 677 F.2d 1061, 1066 (5th Cir. 1982); *Futorian Mfg. Corp. v. Dual Mfg. & Eng'g. Inc.*, 528 F.2d 941, 943 (1st Cir. 1976).

See also P.J. Federico, *Commentary on the New Patent Act*, 75 J. Pat. & Trademark Off. Soc'y 161, 170 (1993) (reprinting commentary to 35 U.S.C. § 1 et seq. (West 1954). One of the "more important" liberalizing changes was Section 256. Lutz, *supra*, at 162. *See also* Frederico, *supra*, at 210 ("Section 256 ... is entirely new.")

Before 1952, a finding that a patent that did not accurately identify inventors could only result in voiding the patent. *MCV, Inc. v. King-Seeley Thermos Co.*, 870 F.2d 1568, 1570 (Fed. Cir. 1989). Thus, prior to the 1952 Act, the *only* purpose for proving joint inventorship in court was to invalidate a patent.[2] Section 256 was enacted to change that common law and preserve patents from invalidity.

> Section 256 is a new section in the law that is correlated with section 116 and relates to a mistake in joining a person as a joint inventor. Very often two or three people make an invention together. They must apply as joint inventors. If they make a mistake in determining who are the true inventors, they do so at their

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[2] *See Pointer v. Six Wheel Corp.*, 177 F.2d 153 (9th Cir. 1949) cited by ICOS as evidence that court's imposed a clear-and-convincing-evidence burden on actions to correct patents prior to the 1952 Act. Opp. at 22. Pointer, accused of infringement, sought to prove joint inventorship for the purpose of invalidating the patent. Likewise the defendant in *Acme Highway Products Corp. v. D.S. Brown Co.*, 431 F.2d 1074 (6th Cir. 1970), whom ICOS suggests unsuccessfully petitioned this Court to review the imposition of a clear-and-convincing-evidence burden on Section 256 claims. Opp. 21.

> peril. This provision permits a bona fide mistake in joining a person as inventor or in failing to join a person as an inventor to be corrected.
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> S. Rep. No. 1979, 82d Cong., 2d Sess., p. 7 (1952).

Iowa State Research Foundation, Inc. v. Sperry Rand Corp., 444 F.2d 406, 408 (4th Cir. 1971) (footnotes omitted). *See also In re Richard N. Bennett*, 766 F.2d 524 (Fed. Cir. 1985) (legislative history of this provision makes clear its remedial intent).

As Congress clearly intended in Section 256 to depart from existing law to preserve patents, there is no basis for concluding that Congress nonetheless intended to impose the heightened burden of proof previously imposed upon parties seeking to invalidate patents. In enacting Section 256 Congress presumably was aware that the burden generally imposed in civil actions is the preponderance-of-the-evidence standard and its silence on the issue suggests that Congress intended that standard be applied. *Grogan v. Garner*, 478 U.S. 279, 286 (1991); *Herman & MacLean v. Huddleston, et al.*, 459 U.S. 375, 390 (1983); *Price Waterhouse v. Hopkins*, 490 U.S. 228, 253 (1989). *See also Abuelhawa v. U.S.*, 129 S. Ct. 2102, 2106 (2009) (legislature is presumed to act with case law in mind). Moreover, because a patent cannot be invalidated through a Section 256 claim, Congress clearly intended a preponderance-of-evidence standard be applied to Section 256 regardless of whether a heightened standard is imposed on infringers seeking to invalidate

patents under Section 282.

The Federal Circuit has repeatedly been asked and has refused to rectify its error with respect to the burden of proof imposed on Section 256 claims.[3] As the question is unlikely to reach any other circuit, only this Court can correct that error. *Pfaff*, 525 U.S. at 60. If this Court fails to address this issue, the continued uncertainty with respect to the appropriate burden will generate unnecessary costs for future Section 256 claimants, opponents, and the courts.

B. Only the District Court Can Determine if the Application of the Preponderance-of-Evidence Standard Will Change the Outcome of Vanderbilt's Claims

ICOS repeatedly argues that the District Court found that it was "equally plausible" that the Vanderbilt scientists did or did not contribute to the conception of the claimed compounds, such that Vanderbilt would not have prevailed even under a preponderance-of-evidence standard. Opp. *passim*. ICOS misrepresents the District Court's findings.

As discussed in the Petition, as part of its case Vanderbilt argued that the evidence showed that the identification of the compound GR30040X was the result of a database search using the structure of the

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[3] ICOS' corporate parent asked the Court of Appeals to correct this error in the context where parallel interference proceedings are pending. *Eli Lilly v. Aradigm Corp.*, 376 F.3d 1352 (Fed. Cir. 2004).

Vanderbilt scientists' novel PDE V inhibitor. Pet. 9-10. That evidence included an English translation of meeting minutes that were inconsistent with ICOS' competing assertion that GR30040X was identified through a search using another compound. Pet. 10.[4] Holding Vanderbilt to a clear-and-convincing-evidence standard, and expressly failing to consider the meeting minutes, the trial court found that the parties' competing assertions with respect to how GR30040X was identified were "equally plausible." Pet. 10; Pet. App. 81a-82a, ¶91. The District Court *never* found that it was only plausible that the Vanderbilt scientists had contributed to the invention. The District Court found that the Vanderbilt scientists contributed and that ICOS' arguments to the contrary were "untenable." Pet. App. 80a, ¶88. *See also* Pet. App. 30a.

Although finding that the District Court erroneously applied a standard for joint invention that required all joint inventors to conceive of the entire claimed invention, the Court of Appeals affirmed the District Court's conclusion that Vanderbilt had failed to prove its claim under a clear-and-convincing-

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[4] At trial ICOS abandoned the story that ICOS and Glaxo had espoused as to how GR30040X was identified, after Vanderbilt proved the story false. Pet. App. 61a – 63a, ¶¶60-64; 70a, ¶¶71-72. ICOS concedes that the October 1992 meeting minutes were inconsistent with ICOS' new story and that an English translation was in evidence. ICOS concedes that the **very first** modification to GR30040X included replacement of the pyridine ring with a phenyl ring **and** electron donating methoxy substituent to create GF173321X, consistent with incorporating the Vanderbilt structure, resulting in significantly increased potency as a PDE V inhibitor, and that further development of GF173321X, not any other attempted GR30040X variations, led to the claimed compounds. Pet. 7-8.

evidence standard. As to whether the outcome would have been different had the District Court applied a preponderance-of-evidence standard, the Court of Appeals stated:

> We express no view on whether Vanderbilt would prevail under a preponderance of the evidence test. Vanderbilt is of course free to seek *en banc* reconsideration of our settled law on this issue.

(App. at 17a-18a, n. 3). Remarkably, ICOS fails to address this statement. Vanderbilt submits that the Court of Appeals would not invite a petition for rehearing if it was clear on the record that the outcome of Vanderbilt's claim would be unchanged under a preponderance-of-evidence standard. That determination should be left to the District Court on remand.

C. Vanderbilt's Case Is the Ideal Vehicle to Resolve the Burden of Proof Issue

Vanderbilt asserted that the preponderance-of-evidence standard should apply to Section 256 before, during, and after trial, and preserved that argument in its appeal and its petition for rehearing. As the Court of Appeals observed, there is clearly a question whether the District Court, applying the preponderance-of-evidence standard and the appropriate test for joint inventorship, would find in favor of Vanderbilt. Thus, Vanderbilt's case is an excellent vehicle for this Court to consider whether the preponderance-of-evidence standard should be applied to Section 256.

Vanderbilt framed its first issue broadly as to whether it is *ever* appropriate for a court to impose a heightened burden of proof on a statutory civil action when there is no evidence Congress intended such a burden. Thus, if the Court grants Vanderbilt's petition the Court's review could extend beyond Section 256 and encompass claims of patent invalidity under Section 282, which the Court has already deemed worthy of review in *Microsoft*. There a number of advantages to the Court reviewing the issue through Vanderbilt's case than through *Microsoft*:

- i4i Limited Partnership has raised issues as to whether Microsoft sufficiently preserved the issue for appeal to this Court.

- The day after the conference in which the Court considered the *Microsoft* petition, the PTO concluded that the prior art references submitted by Microsoft did not create a "substantial new question of patentability," raising questions whether a decision by the Court in *Microsoft* will impact the outcome of that case.

- The Chief Justice recused himself from participating in *Microsoft*, creating a possibility of a split decision.

Vanderbilt's case suffers from none of these potential problems and, therefore, presents a vehicle that is more likely to resolve the burden of proof controversy.

D. A Decision in Favor of the Petitioner in *Microsoft* Will Necessarily Impact Vanderbilt's Case

Even if the Court holds in *Microsoft* that the clear-and-convincing-evidence standard *should* apply to invalidity claims asserted under Section 282, that holding would not control Vanderbilt's case. Validity cannot be attacked through Section 256. Thus the presumption of validity provides no basis for not applying the preponderance-of-evidence standard typically imposed in civil actions. The lower standard is far more consistent with the presumption of validity and Congress' remedial intention that Section 256 claims preserve the validity of patents.

On the other hand, if the Court holds in *Microsoft* that the preponderance-of-evidence standard should be applied to invalidity claims, even if only where the asserted invalidity rests on information not before the PTO, that result will require that a similar burden apply in Section 256 cases. An infringer may assert invalidity under § 282(2) because the applicant "did not himself invent the subject matter sought to be patented" as required under 35 U.S.C. § 102(f). Applicants are not required to submit evidence that they are the only and true inventors, and ICOS stipulated that the PTO undertakes no effort to verify the identity of inventors. Thus, if the Court adopts Microsoft's position, regardless of the rule the Court fashions, alleged infringers asserting invalidity based upon of a failure to list a joint inventor will always have their claims judged against a preponderance-of-evidence standard. Under those circumstances, continued imposition of a clear-and-convincing-

evidence standard on Section 256 claims would be absurd. The idea that it should be harder for a joint inventor to correct and preserve the validity of a patent under Section 256 than for an infringer to invalidate a patent under Section 282 simply cannot be reconciled with the language and legislative history of Section 256 nor the presumption of validity.

The Court should grant Vanderbilt's petition as it is the only means by which the Federal Circuit's error with respect to Section 256 can be rectified. At a minimum, the Court should hold Vanderbilt's petition pending a ruling in *Microsoft* so as to avoid an absurd and unjust result.

II. THE COURT OF APPEALS' FAILURE TO REMAND TO THE DISTRICT COURT IS WORTHY OF REVIEW BY THIS COURT

ICOS' opposition to Vanderbilt's petition with respect to the Court of Appeals' failure to remand is comprised of (1) string cites for the proposition that a Court of Appeals can affirm a District Court on any grounds found in the record; and (2) a rehashing of evidentiary arguments as to why the Court of Appeals might have affirmed the District Court's judgment under a clear-and-convincing-evidence standard. It misses the point of Vanderbilt's argument and this Court's holding in *Pullman-Standard v. Swint*, 456 U.S. 273 (1982). When the District Court considers the evidentiary record against a significantly flawed legal standard, all of the District Court's resulting factual findings become suspect. A Court of Appeals should not ignore the risk that those findings were tainted by the District Court's error and simply apply the correct

legal standard to those "infirm" findings. It should remand the case to the District Court "for further proceedings to permit the trial court to make the missing findings," because "where findings are infirm because of an erroneous view of the law, a remand is the proper course unless the record permits only one resolution of the factual issue." *Pullman-Standard*, 456 U.S. at 291-92.

If the Court wishes to be inundated with the parties' competing evidentiary arguments those can be presented in detail through the briefs and appendix.[5] At this juncture, the important and incontestable points are fairly simple. The District Court measured the evidence against a rule that required a joint inventor to contribute **the entire invention**. The District Court found that the Vanderbilt scientists made a contribution, but as it was not the whole invention, it did not constitute joint invention and thus need not be defined. As Judge Dyk pointed out in his dissent, it was impossible for the remaining members of the panel to apply the appropriate standard to the Vanderbilt contributions. The majority simply ignored those contributions. That may have made it easy for the majority to conclude that there was only one resolution, but it is not the method this Court intended in *Pullman-Standard*. The Court should grant Vanderbilt's petition and review whether the Court of Appeals acted in accordance with that law.

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[5] These will include references to the evidence showing that Vanderbilt's contributions were provided to Dr. Labaudinière, who, in turn, directed Dr. Daugan's work on GR30040X, and that Dr. Daugan was provided extensive portions of the Vanderbilt's scientists' research without any attribution of its source or notice to Vanderbilt.

CONCLUSION

Vanderbilt's petition for writ of certiorari should be granted.

Respectfully submitted this 30TH day of December, 2010,

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